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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,441	05/11/2001	Joachim Spiess	0147-0221P	5077

2292 7590 10/03/2003

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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,441	SPIESS ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence identifiers at each place where a sequence is discussed. See claim 3. This is not meant to be an exhaustive list of places where the specification fails to comply with the sequence rules. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The application cannot issue until it is in compliance. Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are specifically defined, must comply with the sequence rules. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing."

Correction is required.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18, 24, 27-29, 31, to the extent that they are drawn to an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg.

Group II, claim(s) 19-23, 27-29, to the extent that they are drawn to a polynucleotide encoding an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg.

Group III, claim(s) 25-29, to the extent that they are drawn to an antibody against an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg.

Group IV, claim(s) 30, to the extent that it is drawn to use of an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for the preparation of a pharmaceutical composition.

Group V, claim(s) 30, to the extent that it is drawn to use of a polynucleotide encoding an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for the preparation of a pharmaceutical composition.

Group VI, claim(s) 30, to the extent that it is drawn to use of an antibody against an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for the preparation of a pharmaceutical composition.

Group VII, claim(s) 32, to the extent that it is drawn to the use of an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for treating a disorder.

Group VIII, claim(s) 32, to the extent that it is drawn to use of a polynucleotide encoding an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for treating a disorder.

Group IX, claim(s) 32, to the extent that it is drawn to use of an antibody against an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for treating a disorder.

Group X, claim(s) 33, to the extent that it is drawn to use of an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for the investigation of CRFR functions.

Group XI, claim(s) 33, to the extent that it is drawn to use of a polynucleotide encoding an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for the investigation of CRFR functions.

Group XII, claim(s) 33, to the extent that it is drawn to use of an antibody against an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for the investigation of CRFR functions.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In order for the inventions of groups I-XII to have unity of invention it is necessary that the inventive concept be a contribution over the prior art. The inventive concept of groups I-XII is an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg. However, the present specification at the paragraph bridging pages 17-18

discloses that the antagonist astressin is known in the prior art and is an antagonist of CRFR2 and figure 1 in the present specification discloses that astressin lacks the 8 to 10 N-terminal amino acids of Svg. Therefore, an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg cannot be considered novel or cannot be considered to involve an inventive concept. Therefore, the inventions of groups I-XII do not fulfill the requirements for unity of invention. Moreover, polynucleotides, polypeptides, and antibodies do not share a common structural feature and each functions dissimilarly. IN addition, groups IV-XII do not share a special technical feature in that each is directed to an activity that is independent of the other activities.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

claim 5 wherein Xaa_2 is Glu and Xaa_1 is Leu, claim 5 wherein Xaa_2 is His and Xaa_1 is Leu, claim 7 wherein Xaa_1 is Tyr and Xaa_2 is Glu, claim 7 wherein Xaa_1 is Tyr Xaa_2 is His, claim 9, claim 10, claim 12, claim 16, or claim 18.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-18.
The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The inventive concept is an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg. However, the present specification at the paragraph bridging pages 17-18 discloses that the antagonist astressin is known in the prior art and is an antagonist of CRFR2 and figure 1 in the present specification discloses that astressin lacks the 8 to 10 N-terminal amino acids of Svg. Therefore, an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg cannot be considered novel or cannot be considered to involve an inventive concept. .

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

each of the species in claim 32.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 32.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The inventive concept is an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg. However, the present specification at the paragraph bridging pages 17-18 discloses that the antagonist astressin is known in the prior art and is an antagonist of CRFR2 and figure 1 in the present specification discloses that astressin lacks the 8 to 10 N-terminal amino acids of Svg. Therefore, an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg cannot be considered novel or cannot be considered to involve an inventive concept. .

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
OCTOBER 1, 2003